The ABCs of the IRB, IACUC, and IBC: An Overview of Liberty’s Research Ethics Committees

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The IRB

- Respect
- Ethics
- Honesty
- Integrity
RUN THIS BY THE LEGAL DEPARTMENT, BUT RUN SUPER FAST SO THE ETHICS DEPARTMENT DOESN'T SEE IT.
What is the IRB?

• Liberty University’s Institutional Review Board
  – Protects people who take part in research studies affiliated with the university
  – Examines each study’s design to ensure it is
    • Ethical
    • Does not involve unnecessary risks
    • Includes adequate safeguards for participants
Why have an IRB?

• **Biblical Basis**
  – Mark 12:31
    • “You shall love your neighbor as yourself.”
  – Matthew 7:12
    • “Therefore, whatever you want men to do to you, do also to them.”

• **Federally Regulated**
  – Department of Health and Human Services
    • Office for Human Research Protections
    • Food and Drug Administration
Applications, Templates, & Forms
Checklist
Submitting the Application

• Email Materials to the IRB
  – Send to irb@liberty.edu
  – Application must be sent as a Word document
  – Submit a signed signature page
  – Supporting documents as separate Word documents

• Status Email
  – IRB Protocol # is assigned
  – Preliminary review process will begin (~2 weeks)
IRB Review Timeline

Application Submitted to the IRB
Preliminary Review
Revision Cycles
Approval Process
Preliminary Review

• Generally a Two Week Process
  – 1ˢᵗ come, 1ˢᵗ served
• Identify Common Errors
  – Missing Documents, incomplete applications, etc.
• Determine the Review Category
  – Greater than minimal risk will require full committee review
• Revision Emails
  – Request revisions on certain documents in the form of tracked changes and comments
Revision Cycles

• The average is 3 sets of revisions
• Turn-around Time
  – Still 1\textsuperscript{st} come, 1\textsuperscript{st} served
  – Depends on how quickly revisions are returned to the IRB
• Approval Process
  – Begins once revisions and other requirements are completed
Approval Process

• Overall Timeline
  – Most approved within 1-2 months

• Once approved, the researcher will receive
  – IRB Approval Letter
  – IRB-Stamped Consent Form
Class Projects

• Typically do not require IRB approval:
  – Not generalizable data

• IRB approval may be necessary if
  – Data will be presented at a conference
  – Honors project, thesis, or dissertation
  – Research includes special populations (prisoners, children, etc.)
  – Psychologically sensitive data
  – Information regarding illicit activities
Pitfall #1: Student Expectations

• “I need a decision on this by Friday.”
• “The semester is almost over and I have to get my project done soon.”

• Solution:
  1. Understand the IRB Process
  2. Set Realistic Project Timelines (1-2 months)
  3. Start Early
Pitfall #2: Incomplete Applications

- Application lacks information or non-specific information is given:
  - “Informed consent information will be provided.”
    - How will it be distributed?
    - When will it be distributed?
    - How will it be collected?

- **Solution:**
  - “Consent information will be distributed to potential participants via email. Participants will be instructed to return the signed consent document at the time of the interview session.”
  - Read instructions carefully and review applications thoroughly
  - Monitor email for IRB requests
Pitfall #3: Lack of Data Safeguards

According to the anonymous online employee survey, you don't trust management. What's up with that?

Oh, right.
Pitfall #3: Lack of Data Safeguards

• Protections aren’t stated in the application

• Data is not properly protected:

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Admin. Stance</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Carlos Rodriguez</td>
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<td>Anti-Administration</td>
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<tr>
<td>Jason Waters</td>
<td>39</td>
<td>Pro-Administration</td>
</tr>
</tbody>
</table>
Pitfall #3: Lack of Data Safeguards

• **Solution:**
  – Protect the Data:

<table>
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<td>2209</td>
<td>39</td>
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<td>4</td>
</tr>
</tbody>
</table>
Pitfall #3: Lack of Data Safeguards

• Set Specific Safeguards
  – State how you will protect the data in the application

• Examples:
  – Coded data or pseudonyms
  – Locked desk or password-locked computers
  – Store linking list separately
How Can We Help You?

• Department or Course Presentations
  – Specific to the types of research, questions and issues most common in your course/department

• Website Information
  – Ensures students receive most up to date information and templates
  – Department specific page on the IRB website that you can link to directly
Department Specific IRB Pages
Key Points

• Student proposals must be approved by their advisor/chair
  – Methodology
  – Instruments
  – Chair’s Signature

• Use Updated Forms
  – Access from the website
  – Do not give students old forms

• Completed Applications
  – Include all forms:
    • Consent
    • Recruitment
    • Etc.

• General Timeline
  – Can take up to two months
  – Depends on how quickly revisions are received
The IACUC
What is the IACUC?

• The Institutional Animal Care and Use Committee
  – Ensures that all vertebrate animals used for research or instruction at Liberty University are treated ethically and humanely
  – Reviews studies to ensure that the “3 R’s” are upheld
    • Refinement
    • Reduction
    • Replacement
The 3 R’s

• Refinement
  – the use of better techniques, anesthesia, or enrichment, to obtain improved recoveries and outcomes

• Reduction
  – using statistical modeling, or self-controls to limit the number of animals used in research

• Replacement
  – using the lowest order of species possible, or the complete replacement of animals in research
Why have an IACUC?

• Biblical Basis
  – Job 12:7-9
    • “But ask the animals and they will teach you, or the birds in the sky and they will tell you; or speak to the earth, and it will teach you, or let the fish in the sea inform you.”

• Federally Mandated & Regulated
  – USDA & APHIS, NIH & OLAW
Principal Investigator Requirements

• Principal Investigator (PI)
  – Must be a faculty member
  – Students can be co-researchers

• Responsible for:
  – Submitting application & annual review(s)
  – Ensuring proper training and handling
IACUC Review Timeline

Application Received

Preliminary Review

Revision Cycles

Application Sent to Committee/DMR

Committee Issues Decision
Steps for Submitting an Application
IACUC Training/Occupational Health

• **Must** be completed prior to starting work on a protocol
  – Approval will not be granted until complete
  – Applies to ALL personnel
    • Students, Faculty, Staff, etc.
  – Will be verified by the IACUC office
In development, be aware of any changes
  – Check the website for updated information
  – Certain changes will be grandfathered in

Steps:
  – Applicable CITI Training
  – Occupational Health Training/Screening
  – LU-Specific & Lab-Specific Training
Submitting the Application

• Must submit application in a single email to:
  – The IACUC
    • iacuc@liberty.edu
  – The University Veterinarian
    • dmceguirt@liberty.edu

• Must submit at least 2 weeks prior to next scheduled IACUC meeting
Status Email & Training

• Status Email
  – Sent once application has been processed
  – Includes instructions on completing any additional training
    • PI or associated personnel
  – Indicates a timeline for preliminary review
    • Generally a 2 week process
Preliminary Review

• **Veterinary Review**
  – Focuses on animal care and use
  – Number, species, procedures, methods, medications, etc.

• **Administrative Review**
  – Focuses on “completeness”
  – Verifies training status and ensures all documents have been submitted
Revision Cycles

• 1\textsuperscript{st} come, 1\textsuperscript{st} served
  – Depends on how quickly revisions are returned to the IACUC

• Once all revisions are received, applications will be forwarded to the committee
  – Full Committee Review
  – Designated Member Review
Approval Process

• Depends on the type of study/review:
  – Most are approved within 2 months if revisions are received in a timely manner

• Approval letters will be sent to the Principal Investigator via email
Annual & 3-Year Renewals

• Annual Renewal
  – A “status update” must be provided yearly prior to the study expiration date
    • Annual Review Form

• 3-Year Renewal
  – Must submit a new protocol application, indicating that it is a continuation
    • New/3-Year Protocol Form
Protocol Closure

• Closure Form
  – If you complete your work, we need to know
  – Verifies animals were disposed of properly
  – Documents any transfer to other protocols
Post-Approval Monitoring

• Ensures Compliance
  – Occurs randomly to verify:
    • Any changes (procedures, staff, PI, animal #, etc.)
      – Be sure to submit appropriate change forms so that you are NOT caught in PAM process
    • Protocol is implemented as approved

• Non-compliance can result in revocation of approval
  – Depends on the severity of the issue
  – We will work with you to ensure you remain compliant
Key Points

• Principal Investigator
  – Students cannot serve as the PI
  – Bears responsibility for training aspects

• Submit applications in a single email to:
  – iacuc@liberty.edu
  – dcmguirt@liberty.edu

• Annual/3 Year Renewals
  – Keep us updated!

• Timeline
  – Generally 2 months
  – Respond promptly to revision requests

• Personnel
  – We need to know when personnel are added or removed. (Use form)

• Questions?
  – Use the website or contact us!
What is the IBC?
What is the IBC?

• The Institutional Biosafety Committee
  – Provides oversight for all research involving the use of recombinant or synthetic DNA molecules and biohazardous materials
  – Reviews studies to ensure:
    • Appropriate Safety & Training
    • Adequate Facilities
    • Environmental Impact
More Information Available Online

• Liberty University IRB
  – [www.liberty.edu/irb](http://www.liberty.edu/irb)

• Liberty University IACUC
  – [www.liberty.edu/iacuc](http://www.liberty.edu/iacuc)

• Liberty University IBC
  – [www.liberty.edu/ibc](http://www.liberty.edu/ibc)
Contact Us

• Liberty University IRB
  – 434-592-5530
  – irb@liberty.edu

• Liberty University IACUC
  – 434-582-2827
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• Liberty University IBC
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  – ibc@liberty.edu
Questions?